

### ***Remarks***

Upon entry of this amendment, claims 37-39, 42-49, and 52-57 will be pending in the instant application.

Applicants thank the Examiner for indicating that SEQ ID NO:15 and homologs of at least 95% identity or higher that have protease activity are allowable.

Applicants have canceled claims 19, 40-41, and 50-51 without prejudice or disclaimer. Claim 37 has been amended to delete recitation to the subject matter of amino acid residues 428 to 437 of SEQ ID NO:15. Claims 37 and 47 have been amended to delete recitation to the amino acid sequence of the ADAM polypeptide encoded by the cDNA contained in IFO Accession No. IFO 16173. Claim 47 has also been amended to recite that the first amino acid sequence has 95% or higher identity to the second amino acid sequence. Applicants reserve the right to pursue the canceled subject matter in later-filed continuing applications.

Accordingly, no new matter has been added and entry of this amendment is respectfully requested.

#### **I. Written Description Rejections Under 35 U.S.C. § 112, First Paragraph**

(a) The Examiner has rejected claims 37-46 under 35 U.S.C. § 112, first paragraph for alleged lack of written of description. In particular, the Examiner alleges that "a genus of polypeptides comprising merely residues 428-437 of SEQ ID NO:15 ... are not adequately described in the specification." See, page 4, fourth paragraph.

Although Applicants do not acquiesce to the instant rejection, the subject matter directed to polypeptides comprising the amino acid residues 428 to 437 of SEQ ID NO:15 has been canceled without prejudice or disclaimer, thereby rendering the rejection of these claims moot. Applicants retain the right to pursue the canceled subject matter in one or more continuing applications. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

(b) The Examiner has rejected claims 47-57 under 35 U.S.C. § 112, first paragraph for alleged lack of written description. In particular, the Examiner alleges that this the instant application lacks disclosure for the term 90% or more identical to SEQ ID NO:15 and that the specification fails to adequately describe "variants having at least 90%

identity to SEQ ID NO:15." See, pages 5-6.

Although Applicants do not acquiesce to the instant rejection, claim 47 has been amended to recite 95% or higher identity, rather than 90%. Thus, the rejection of these claims is rendered moot. Applicants retain the right to pursue the canceled subject matter in one or more continuing applications. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection. Applicants note that claim 47 now corresponds to subject matter identified by the Examiner as allowable. See page 9.

c. The Examiner has also rejected claims 37-58 under 35 U.S.C. § 112, first paragraph for failing to comply with the written description requirement in that the claims allegedly fail to comply with the deposit requirement rules. In particular, the Examiner alleges that "the applicants have deposited the organisms but there is no indication in the specification as to the public availability." See, page 8, third paragraph.

Applicants preliminarily note that the subject matter directed to the amino acid sequence of the ADAM polypeptide encoded by the cDNA contained in IFO Accession No. IFO 16173 has been canceled without prejudice or disclaimer. Applicants respectfully retain the right to pursue the canceled subject matter in later-filed continuing applications.

In response, Applicants' representative hereby gives the following assurance by signature below:

Takeda Chemical Industries, Ltd., the assignee of the present application, has deposited biological material under the terms of the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure with the following International Depository Authority: National Institute of Bioscience and Human Technology (NIBH), Agency of Industrial Science and Technology, now known as International Patent Organism Depositary (IPOD), AIST Tsukuba Central 6, 1-1, Higashi 1-chome, Tsukuba-shi, Ibaraki-Ken 305-8566 Japan (present address). The deposit was made on August 26, 1998, accepted by the NIBH (now IPOD), and given NIBH Accession Number FERM BP-6474. In accordance with M.P.E.P. § 2410.01 and 37 C.F.R. § 1.808, assurance is hereby given that all restrictions on the availability to the public of NIBH Accession Number FERM BP-6474 will be irrevocably removed upon the grant of a patent based on the instant application, except as permitted under 37 C.F.R. § 1.808(b). A partially redacted copy of the NIBH Receipt in the Case for an Original Deposit for Accession Number NIBH is enclosed herewith as Exhibit A.

Applicants submit that the rejections under 35 U.S.C. 112, first paragraph, have been overcome or obviated by the above amendments and statements. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

## **II. Enablement Rejections Under 35 U.S.C. § 112, First Paragraph**

a. The Examiner has rejected claims 37-47 under 35 U.S.C. § 112, first paragraph for alleged lack of enablement. In particular, the Examiner has alleged that the specification fails to teach which residues other than those corresponding to residues 428-437 of SEQ ID NO:15 must be incorporated in polypeptides of claim 37(b) and claim 39 such that they will be able to retain the appropriate three dimensional structure for protease activity. No examples of such polypeptides or residues within such polypeptides are provided either. Current state of the prior art indicates that 437-428=9 polypeptides are totally incapable of retaining any function.

See, page 7, first paragraph.

Although Applicants do not acquiesce to the instant rejection, the subject matter directed to polypeptides comprising the amino acid residues 428 to 437 of SEQ ID NO:15 has been canceled without prejudice or disclaimer, thereby rendering the rejection of these claims moot. Applicants retain the right to pursue the canceled subject matter in one or more continuing applications. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

b. The Examiner has also rejected claims 47-57 under 35 U.S.C. § 112, first paragraph for alleged lack of enablement. In particular, the Examiner alleges that the "current state of the prior art indicates that any polypeptide which happens to have at least 90% identity to that encoding a full-length polypeptide is not necessarily capable of retaining the activity of said full-length polypeptide." See, page 7, paragraph 4.

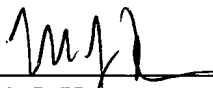
Although Applicants do not acquiesce to the instant rejection, the subject matter directed to 90% identity to SEQ ID NO:15 has been amended to 95% or higher identity as noted in section I(b) above. Thus, the rejection of these claims is rendered moot. Applicants retain the right to pursue the canceled subject matter in one or more continuing applications. Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection. Applicants note that claim 47 now corresponds to subject matter identified by the Examiner as allowable. See page 9.

### *Conclusion*

Applicants respectfully request that the above-made remarks and amendments be entered and made of record in the file history of the instant application. In view of the foregoing remarks, Applicants believe that this application is now in condition for allowance, and an early notice to that effect is urged. The Examiner is invited to call the undersigned at the phone number provided below if any further action by Applicants would expedite the allowance of this application. If there are any fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an additional extension of time under 37 C.F.R. § 1.136, such an extension is requested and the fee should also be charged to our Deposit Account.

Dated: October 27, 2004

Respectfully submitted,

By   
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KKH/MJH/KC/lcc



国際様式

INTERNATIONAL FORM

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

特許手続上の微生物の寄託の国際的承認  
に関するブダペスト条約

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

下記国際寄託当局によって規則7.1に従い  
発行される。

issued pursuant to Rule 7.1 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified at the bottom of this  
page.

## 原寄託についての受託証

氏名 (名称)

武田薬品工業株式会社  
代表者 武田 國男

殿

寄託者

あて名

大阪市中央区道修町四丁目1番1号

### 1. 微生物の表示

(寄託者が付した識別のための表示)

*Escherichia coli* DH5a/pJB2052

(受託番号)

FERM BP- 6474

### 2. 科学的性質及び分類学上の位置

1 桶の微生物には、次の事項を記載した文書が添付されていた。

- 科学的性質
- 分類学上の位置

### 3. 受領及び受託

本国際寄託当局は、平成10年 8月26日 (原寄託日) に受領した1桶の微生物を受託する。

### 4. 移管請求の受領

本国際寄託当局は、  
年 月 日 (原寄託日) に1桶の微生物を受領した。  
そして、年 月 日に原寄託よりブダペスト条約に基づく寄託への移管請求を受領した。

### 5. 国際寄託当局

通商産業省工業技術院生命工学工業技術研究所

名称: National Institute of Bioscience and Human-Technology  
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平成10年 (1998) 8月26日